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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/263,689	03/05/1999	JIAN NI	1488.0560002	2137

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EXAMINER	
CANELLA, KAREN A.	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/263,689	Ni et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Dec 11, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *3 months* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

4. ☒ Applicant's reply has overcome the following rejection(s):
   none

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   see attached

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
   Claim(s) allowed: *none*
   Claim(s) objected to: *none*
   Claim(s) rejected: *90-114, 116-121, 124-133, and 136-140*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). *3* .

11. ☐ Other:

Response to Arguments

1. Claims 122, 123, 134 and 135 have been canceled. Claims 121 and 133 have been amended.

2. Claims 90-114, 116-121, 124-133 and 136-140 remain rejected under 35 U.S.C. 101 and 35 U.S.C. 112.

3. The drawings submitted November 20, 2000 have been approved and entered into the application.

4. Applicant argues that the claimed Galectin-9 (SEQ ID NO:4) has utility as it is identical to ecalectin with the exception an addition of 12 consecutive amino acids which are present as amino acids 149 to 160 of SEQ ID NO:4. Applicant further argues that SEQ ID NO:4 is identical to the Galectin-9 of Tureci with the exception of an addition of 44 consecutive amino acids from residues 149 to 192 of SEQ ID NO:4. Ecalectin and the Galectin-9 of Tureci are known in post-filing date art to function as a novel eosinophil chemoattractants which are produced by activated T-lymphocytes. Applicant asserts that SEQ ID NO:4 would then have utility in the diagnosis of asthma as one of skill in the art would use SEQ ID NO:4 to raise antibodies for the detection of asthma or Hodgkin's disease. This has been considered but not found persuasive. Firstly, one of skill in the art would use ecalectin to raise antibodies that bind to ecalectin and the Galectin-9 of Tureci (which is not the Galectin 9 of the instant specification) to raise antibodies to the Galectin-9 of Tureci, not as asserted by applicant, SEQ ID NO:4 which contains extraneous amino acids not found in ecalectin or the Galectin-9 of Tureci. Secondly, although it is postulated in the art that ecalectin or Galectin-9 of Tureci function together with Il-5 and GM-CSF to stimulate eosinophil extravasion in tissues, this is part of a general immune response caused by T-cell mediated inflammatory reactions in humans and not specifically confined to asthma or Hodgkin's disease. Applicant has argued that Galectin-9 of Tureci is an antigen that is selectively expressed by patients with Hodgkin's lymphoma. This is not

persuasive, as a subset of patients having Hodgkin's disease had antibodies that reacted with Galectin-9 only because of the heightened immune response in the lymph tissue of these patients caused a loss of tolerance to this protein which was expressed in the peripheral blood leukocytes and lymphatic tissues of normal individuals. The art of record provides no support for a method wherein the detection of the Galectin-9 of Tureci or ecalectin would be diagnostic for Hodgkin's disease or asthma. Furthermore, neither the specification nor any art of record has described SEQ ID NO:4 as having chemokine properties or as being overexpressed in Hodgkin's disease or asthma. The specification states on page 29:

"The present invention is useful for detecting diseases in mammals (for example, cancer, autoimmune diseases, inflammatory diseases, asthma, and allergic diseases). In particular the invention is useful during the diagnosis of the following types of cancers in mammals: melanoma, renal astrocytoma, Hodgkin disease, breast, ovarian, prostate, bone, liver, lung, pancreatic, and spleenic."

This listing of unrelated diseases cannot be considered as enablement for a method of diagnosis without objective evidence that SEQ ID NO:4 is selectively or differentially expressed in these diseases . It is also observed that cancers involving other than those involving lymph tissue or blood are included with Hodgkin's disease. Further, the specification provides no molecular mechanism of action of SEQ ID NO:4 to provide a nexus to a disease state involving eosinophiles.

Applicant is reminded that the cited references represent information that was not available at the time of the instant invention. As the specification, or pre-filing date art must be enabling for the instant invention, developments occurring after the filing date cannot be considered of consequence. See In re Wright, 27 USPQ 1510, 1514 (Fed. Cir. 1993).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are

unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

January 28, 2002

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